

PSJ3
Exhibit 378

From: BILL WILSON <wssinc@verizon.net>
Sent: Wednesday, February 06, 2008 5:30 AM
To: Ducca, Anita
Subject: Discussion intro
Attachments: 2069529921-HDMA discussion points header.doc

Anita,
Here is the discussion header. I used the same language you did on the draft. I will call you tomorrow around 9AM your time.

William S. Wilson, CPP, CFI
President
Wilson Security Services, Inc.
800-535-8838

The information contained in this document: "Discussion Draft, HDMA Best Practices for Controlled substances (CS) Suspicious Orders" is a review draft intended for HDMA members only. This document does not represent HDMA policy, recommendations, or standards. All materials and statements contained in this document are preliminary, will be used for discussion purposes only, and should not be distributed outside of the recipient's own company.

1st D R A F T

History

In 1970 Congress enacted into law the Controlled Substances Act (CSA). It was part of Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970. The CSA is the legal basis by which the manufacture, importation, possession and distribution of certain drugs are regulated by the federal government. Two federal departments, the Department of Justice (DEA) and the Department of Health and Human Services (FDA) implement the regulations. The CSA also created a closed system of distribution for those authorized to handle controlled substances. Since its enactment in 1970 the Act has been amended several times:

- The Psychotropic Substances Act of 1978
- The Controlled Substances Penalties Amendments Act of 1984
- The Chemical Diversion and Trafficking Act of 1988
- The Domestic Chemical Diversion and Control Act of 1993
- The Federal Analog Act
- The Methamphetamine Precursor Control Act which was superseded by the Combat Methamphetamine Epidemic Act of 2005

The regulations outlined in Title 21, United States Code part 1300 to end contains the rules and regulations for all individuals and firms desiring to conduct business in controlled substances. All individuals and firms must be registered with the DEA and are required to maintain complete and accurate inventories and records of all transactions involving controlled substances as well as security for the storage of controlled substances.

One major requirement under the above entitled code places a duty upon distributors to report suspicious orders of controlled substances. Title 21, United States Code section 1301.74 (b) states that "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

Up until now DEA has interpreted this section to require distributors to design and operate a system to identify and report suspicious orders based on the regulation's definition of "suspicious". Once the orders were identified as suspicious, under their definition, the only other requirement was to report the order to the DEA.

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Recently, and without any due process for rule changes, DEA has expanded the definition of suspicious orders to include those that the registrant may have "reason to believe the order will be diverted". In addition to the expansion of the definition DEA has placed an increased burden on distributors to stop shipments of suspicious orders of controlled substances. They have also proceeded against distributors registrations based on alleged activities "not in the best interests of the public".

In three public statements to Congressional Committees on December 13, 2005, July 26, 2006 and September 18, 2007, the DEA Administrator has spoken about "the growing problem of the diversion and abuse of controlled pharmaceuticals continues to be one of the top priorities of the Drug Enforcement Administration. . . We have also used our regulatory authority to take action against DEA registrants found to be in violation of regulatory requirements under the CSA. Through regulatory authority, DEA has subjected registrants to significant civil fines, licensing restrictions, or even suspended registrations. Such civil remedies have proven to be an effective deterrent to potential violators."

DEA seems to have taken the position that if the registrant did not know their customer was diverting they SHOULD have known and have attached severe penalties to not knowing. That is the purpose of the following discussion points regarding knowing your customer, identifying and reporting suspicious orders of controlled substances and training everyone who comes into contact with controlled substances.